



National Institutes of Health
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CHARTER

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

AUTHORITY

Section 3(d) of Public Law 106-545, 42 U.S.C.285I-3(d), as amended. The Scientific Advisory Committee on Alternative Toxicological Methods (Committee) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Committee will provide advice to the Director, National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP), the Interagency Coordination Committee on the Validation of Alternative Methods (ICCVAM), and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding ICCVAM activities. The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) also advises the NIEHS and NICEATM on NICEATM activities. The purposes of the ICCVAM as defined in the law are to increase the efficiency and effectiveness of Federal agency test method review; eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies; optimize utilization of scientific expertise outside the Federal government; ensure that new and revised test methods are validated to meet the needs of Federal agencies; and reduce, refine, or replace the use of animals in testing, where feasible. NICEATM supports activities and collaborates with ICCVAM to facilitate the development, scientific review, validation, and interagency consideration of novel toxicological methods of multiagency interest that predict human health risks while reducing, refining, and/or replacing animal tests. NICEATM promotes participation and communication with stakeholders throughout the process of test method development and validation.

DESCRIPTION OF DUTIES

SACATM will provide advice on activities and directives relating to NICEATM's support of ICCVAM and communication and outreach, as well as activities regarding the following statutorily mandated ICCVAM functions: (1) Review and evaluate new or revised or alternative test methods, including batteries of tests and test screens that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised or alternative test methods of interagency interest; (2) Facilitate appropriate interagency and international harmonization of acute or chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods; (3) Facilitate and provide guidance on the development of validation criteria, validation studies, and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders; (4) Submit

ICCVAM test recommendations for the test methods reviewed by the ICCVAM, through expeditious transmittal by the Secretary of HHS (or the designee of the Secretary), to each appropriate Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for test methods, including batteries of tests and test screens for chemicals or classes of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods; (5) Consider for review and evaluation petitions received from the public that-- (A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and (B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method; (6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the response from the agencies regarding these recommendations; and (7) Prepare reports to be made available to the public on its progress under the Act.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee will advise, assist, consult with, and make recommendations to the Director, NIEHS and NTP, ICCVAM, and NICEATM.

SUPPORT

Management and support services will be provided by the NTP Office of Liaison, Policy, and Review, NIEHS, and NICEATM.

ESTIMATED ANNUAL OPERATING COST AND STAFF YEARS

The estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is \$87,232. The estimated annual person-years of staff support required is 0.6, at an estimated annual cost of \$78,426.

DESIGNATED FEDERAL OFFICER

The Director, NIEHS and NTP, will assign a full-time or permanent part-time NIEHS employee as the Designated Federal Officer (DFO) of the Committee. In the event that the DFO cannot fulfill the assigned duties of the Committee, one or more full-time or permanent part-time NIEHS or NIH employees will be assigned these duties on a temporary basis.

The DFO will approve or call all of the Committee's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Committee and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIEHS and NTP.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Committee will be held not less than one time within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary of Health and Human Services (Secretary) in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made

during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing. This Committee is mandated with no specified end date.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for the Scientific Advisory Committee on Alternative Toxicological Methods will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee will consist of 15 members, including the Chair, appointed by the Director, NIEHS and NTP. The Committee will include representatives from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories. Knowledgeable representatives from public health, environmental communities, or organizations using new or alternative test methodologies may be included as appropriate. There will be at least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of the following categories: (1) personal care, pharmaceutical, industrial chemicals, or agricultural industry; (2) any other industry that is regulated by one of the Federal agencies on ICCVAM; and (3) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986.

All non-Federal members serve as Special Government Employees. Members and the Chair will be invited to serve for overlapping three or four-year terms. Members may serve after the expiration of their terms until a successor has been appointed. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members. The membership of SACATM will include, as nonvoting *ex officio* members, the agency heads or their designees from the Federal agencies represented on ICCVAM. International regulatory and/or international research organizations may also be invited to designate a liaison member to SACATM. Liaison members will not have voting privileges.

SUBCOMMITTEES

As necessary, subcommittees and *ad hoc* working groups may be established by the DFO within the Committee's jurisdiction. The advice/recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. *Ad hoc* consultants do not count towards the quorum and may not vote. A quorum for a subcommittee will be three members. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records will be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

December 18, 2011

APPROVED:

11-8-11

Date

REDACTED

Director, NIEHS and NTP

PROPOSED PLAN FOR APPROPRIATE BALANCE OF COMMITTEE MEMBERSHIP

The Scientific Advisory Committee on Alternative Toxicological Methods members will consist of 15 members, including the Chair, who are knowledgeable of the issues related to the committee's function. Members will include representatives from outstanding authorities from an academic institution, a State government agency, corporations or organizations developing, marketing, or using new or revised or alternative test methodologies, including contract laboratories. Knowledgeable representatives from public health, environmental, or international communities may also be included as appropriate and one knowledgeable representative with a history of expertise, development, or evaluation of new, revised, or alternative test methods from: (1) the personal care, pharmaceutical, industrial chemicals, or agricultural industry; (2) any other industry that is regulated by one of the Federal agencies on the ICCVAM; and (3) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986.

The NIH will give close attention to equitable geographic distribution and to ethnic and gender representation so long as the effectiveness of the Committee is not impaired.

Appointments will be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, disability, cultural, religious, or socioeconomic status.

NOTICE OF RECHARTER
SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE
TOXICOLOGICAL METHODS

This Committee was established by statute and has functions which are of a continuing nature so that its duration is not governed by section 14(a) of the Federal Advisory Committee Act but is otherwise provided for by law. The Committee is hereby rechartered in accordance with section 14(b)(2) of that Act.

11-8-11

Date

REDACTED

Director, NIEHS